



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0973]

Revocation of Three Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection and/or Diagnosis of COVID-19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to the University of Texas MD Anderson Cancer Center, Molecular Diagnostics Laboratory (MD Anderson) for the MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay, and Visby Medical, Inc. for the Visby Medical COVID-19 and Visby Medical COVID-19 Point of Care Test. FDA revoked these Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

DATES: The Authorization for the MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay is revoked as of November 30, 2022. The Authorizations for the Visby Medical COVID-19 and Visby Medical COVID-19 Point of Care Test are revoked as of December 2, 2022.

ADDRESSES: Submit written requests for a single copy of the revocations to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revocations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocations.

FOR FURTHER INFORMATION CONTACT: Jennifer Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993-0002, 301-796-8510 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub. L. 108-276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On June 24, 2020, FDA issued an EUA to MD Anderson for the MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on November 20, 2020 (85 FR 74346), as required by section 564(h)(1) of the FD&C Act. On September 16, 2020, FDA issued an EUA to Visby Medical, Inc. for the Visby Medical COVID-19, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on April 23, 2021 (86 FR 21749), as required by section 564(h)(1) of the FD&C Act. On February 8, 2021, FDA issued an EUA to Visby Medical, Inc. for the Visby Medical COVID-19 Point of Care Test, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on April 23, 2021 (86 FR 21749), as required by section 564(h)(1) of the FD&C Act. Subsequent revisions to the Authorizations were made available on FDA's website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the

FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. EUA Revocation Requests

On November 18, 2022, FDA received a request from MD Anderson for the withdrawal of, and on November 30, 2022, FDA revoked, the Authorization for the MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay. Because MD Anderson requested FDA withdraw the EUA for the MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization. On November 29, 2022, FDA received a request from Visby Medical, Inc. for the closure of, and on December 2, 2022, FDA revoked, the Authorizations for the Visby Medical COVID-19 and Visby Medical COVID-19 Point of Care Test. Because Visby Medical, Inc. requested FDA close the EUAs for the Visby Medical COVID-19 and Visby Medical COVID-19 Point of Care Test, FDA has determined that it is appropriate to protect the public health or safety to revoke these Authorizations.

III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at <https://www.regulations.gov/>.

IV. The Revocations

Having concluded that the criteria for revocation of the Authorizations under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUAs for MD Anderson's MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay and for Visby Medical, Inc.'s Visby Medical COVID-19 and Visby Medical COVID-19 Point of Care Test. The revocations in their entirety follow and provide an explanation of the reasons for each revocation, as required by section 564(h)(1) of the FD&C Act.



November 30, 2022

Keyur P. Patel, Ph.D.
Medical Director, Molecular Diagnostics Laboratory
The University of Texas MD Anderson Cancer Center
6565 MD Anderson Blvd.
Houston, TX 77030

Re: Revocation of EUA200158

Dear Dr. Patel:

This letter is in response to the request from the University of Texas MD Anderson Cancer Center, Molecular Diagnostics Laboratory, received via email on November 18, 2022, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay issued on June 24, 2020, and amended on September 23, 2021 and November 29, 2021. The University of Texas MD Anderson Cancer Center, Molecular Diagnostics Laboratory discontinued testing with the MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay as of October 31, 2022.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because the University of Texas MD Anderson Cancer Center, Molecular Diagnostics Laboratory has requested FDA withdraw the EUA for the MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200158 for the MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration



December 2, 2022

Beth Lingenfelter
VP of Clinical and Regulatory Affairs
Visby Medical, Inc.
3010 North First Street
San Jose, CA 95134

Re: Revocation of EUA202677

Dear Ms. Lingenfelter:

This letter is in response to the request from Visby Medical, Inc., received via email on November 29, 2022, that the U.S. Food and Drug Administration (FDA) close the EUA for the Visby Medical COVID-19 issued on September 16, 2020, amended on December 28, 2020, and reissued on August 31, 2021. Visby Medical, Inc. discontinued manufacturing the Visby Medical COVID-19 test on January 25, 2021, and FDA understands there are no viable (non-expired) Visby Medical COVID-19 tests remaining in distribution in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Visby Medical, Inc. has requested FDA close the EUA for the Visby Medical COVID-19, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202677 for the Visby Medical COVID-19, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Visby Medical COVID-19 is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration



December 2, 2022

Beth Lingenfelter
VP of Clinical and Regulatory Affairs
Visby Medical, Inc.
3010 North First Street
San Jose, CA 95134

Re: Revocation of EUA203089

Dear Ms. Lingenfelter:

This letter is in response to the request from Visby Medical, Inc., received via email on November 29, 2022, that the U.S. Food and Drug Administration (FDA) close the EUA for the Visby Medical COVID-19 Point of Care Test issued on February 8, 2021, amended on September 23, 2021, and reissued on July 22, 2022. Visby Medical, Inc. discontinued manufacturing the Visby Medical COVID-19 Point of Care Test on April 25, 2022, and FDA understands there are no viable (non-expired) Visby Medical COVID-19 Point of Care Tests remaining in distribution in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Visby Medical, Inc. has requested FDA close the EUA for the Visby Medical COVID-19 Point of Care Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA203089 for the Visby Medical COVID-19 Point of Care Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Visby Medical COVID-19 Point of Care Test is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration

Dated: December 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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